



BILLING CODE: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-16-0850; Docket No. CDC-2015-0093]

**Proposed Data Collection Submitted for Public Comment and
Recommendations**

AGENCY: Centers for Disease Control and Prevention (CDC),
Department of Health and Human Services (HHS)

ACTION: Notice with comment period

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on the proposed extension of the Laboratory Response Network information collection.

DATES: Written comments must be received on or before [INSERT]

DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2015-0093 by any of the following methods:

- Federal eRulemaking Portal: Regulation.gov. Follow the instructions for submitting comments.
- Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to Regulations.gov, including any personal information provided. For access to the docket to read background documents or comments received, go to Regulations.gov.

Please note: All public comment should be submitted through the Federal eRulemaking portal (Regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and

Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on

respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project

Laboratory Response Network - Extension - (OMB Control No. 0920-0850, expires April 30, 2016), National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Laboratory Response Network (LRN) was established by

the Department of Health and Human Services (HHS), Centers for Disease Control and Prevention (CDC) in accordance with Presidential Decision Directive 39, which outlined national anti-terrorism policies and assigned specific missions to Federal departments and agencies. The LRN's mission is to maintain an integrated national and international network of laboratories that can respond to suspected acts of biological, chemical, or radiological threats and other public health emergencies.

When Federal, State and local public health laboratories voluntarily join the LRN, they assume specific responsibilities and are required to provide information to the LRN Program Office at CDC. Each laboratory must submit and maintain complete information regarding the testing capabilities of the laboratory. Biennially, laboratories are required to review, verify and update their testing capability information. Complete testing capability information is required in order for the LRN Program Office to determine the ability of the Network to respond to a biological or chemical threat event. The sensitivity of all information associated with the LRN requires the LRN Program Office to obtain personal information about all individuals accessing the LRN Web site. In addition, the LRN Program Office must be able to contact all laboratory personnel

during an event so each laboratory staff member that obtains access to the restricted LRN Web site must provide his or her contact information to the LRN Program Office.

As a requirement of membership, LRN Laboratories must report all biological and chemical testing results to the LRN Program at CDC using a CDC developed software tool called the LRN Results Messenger. This information is essential for surveillance of anomalies, to support response to an event that may involve multiple agencies and to manage limited resources. LRN Laboratories must also participate in and report results for Proficiency Testing Challenges or Validation Studies. LRN Laboratories participate in multiple Proficiency Testing Challenges, Exercises and/or Validation Studies every year consisting of five to 500 simulated samples provided by the LRN Program Office. It is necessary to conduct such challenges in order to verify the testing capability of the LRN Laboratories. The rarity of biological or chemical agents perceived to be of bioterrorism concern prevents some LRN Laboratories from maintaining proficiency as a result of day-to-day testing. Simulated samples are therefore distributed to ensure proficiency across the LRN. The results obtained from testing these simulated samples must also be entered into Results Messenger for evaluation by the LRN Program Office.

During a surge event resulting from a bioterrorism or chemical terrorism attack, LRN Laboratories are also required to submit all testing results using LRN Results Messenger. The LRN Program Office requires these results in order to track the progression of a bioterrorism event and respond in the most efficient and effective way possible and for data sharing with other Federal partners involved in the response. The number of samples tested during a response to a possible event could range from 10,000 to more than 500,000 samples depending on the length and breadth of the event. Since there is potentially a large range in the number of samples for a surge event, CDC estimates the annualized burden for this event will be 2,250,000 hours or 625 responses per respondent.

There is no cost to the respondents other than their time. The total estimated annualized burden is 2,382,300 hours.

Estimated Annualized Burden Hours

Respondents	Forms	Number of Respondents	Average Number of Responses per Respondent	Average Burden Per Response (hours)	Total Burden Hours
Public Health Laboratories	Biennial Requalification	150	1	2	300
Public Health Laboratories	General Surveillance Testing Results	150	25	24	90,000
Public Health Laboratories	Proficiency Testing/Validation Testing Results	150	5	56	42,000
Public Health Laboratories	Surge Event Testing Results	150	625	24	2,250,000
Total					2,382,300

Leroy A. Richardson,
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Office of Scientific Integrity,
Office of the Associate Director for Science,
Office of the Director,
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